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Office of Regulatory Policy  
HFD - 7  
5600 Fishers Lane (Rockwall II Rm. 1101)  
Rockville, MD 20857

Attention: Beverly Friedman

Dear Ms. Axelrad:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 5,284,858. The application was filed on March 27, 2006, under 35 U.S.C. § 156.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term extension. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7754 (telephone) or (571) 273-7754 (facsimile).

Kathleen Kahler Fonda  
Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: Bruce E. Kramer  
Sughrue Mion PLLC  
2100 Pennsylvania Avenue, NW  
Suite 800  
Washington, DC 20037-3213

RE: AMITIZA™ (lubiprostone)  
FDA Docket No. 2006E-0355